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BAG FOR PERITONEAL DIALYSIS

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[There are no amendments to this patent.]

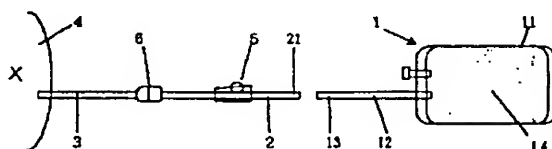
## Abstract

### Objective

The objective of this invention is to eliminate the bag for waste fluid and to reduce the amount of waste produced in the continuous ambulatory peritoneal dialysis (CAPD) operation without causing peritonitis or other infections.

### Means to solve

A type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube; the connecting tube and an exchange tube (connected to the peritoneal tube) are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through the exchange tube into the peritoneal cavity, the connecting tube and exchange tube are separated aseptically, the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept inside the peritoneal cavity; after a prescribed dwell time, the connecting tube and exchange tube are aseptically spliced, and, after the used peritoneal dialyzing fluid is removed to the bag via the exchange tube, the connecting tube and the exchange tube are separated aseptically.



## Claims

1. A type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube; for this bag, the connecting tube and another tube are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through said another tube, the connecting tube and said another tube are separated aseptically, the aseptic state in the bag, which has become empty, is maintained; after a prescribed dwell time in this state, the connecting tube and said another tube are aseptically spliced, and, after the used peritoneal dialyzing fluid is removed to the bag via said another tube, the connecting tube and said another tube are separated aseptically.

2. A type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube for connection to a tube passing into the peritoneal cavity; for this bag, the connecting tube and said tube passing into the peritoneal cavity are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through said tube passing into the peritoneal cavity, the connecting tube and said tube passing into the peritoneal cavity are

separated aseptically, the aseptic state in the bag, which has become empty, is maintained; after a prescribed dwell time in this state, the connecting tube and said tube passing into the peritoneal cavity are aseptically spliced, and, after the used peritoneal dialyzing fluid is removed to the bag via said tube passing into the peritoneal cavity, the connecting tube and said tube passing into the peritoneal cavity are separated aseptically.

3. A type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid, and it has a connecting tube;

for this bag, a portion of said connecting tube and a portion of another tube are melted and cut by a heated wafer, and the cut surfaces are fused to each other to realize aseptic splicing; after the peritoneal dialyzing fluid is emptied from the bag through said another tube, a portion of the connecting tube and a portion of said another tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing, and the aseptic state in the bag, which has become empty, is maintained;

after a prescribed dwell time in this state, a portion of the connecting tube and a portion of said another tube are melted and cut by said heated wafer and the cut surfaces are fused to each other to realize aseptic splicing; and, after the used peritoneal dialyzing fluid is removed to the bag via said another tube, a portion of the connecting tube and a portion of said another tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing.

4. A type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid, and it has a tube passing into the peritoneal cavity;

for this bag, a portion of said connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by a heated wafer, and the cut surfaces are fused to each other to realize aseptic splicing; after the peritoneal dialyzing fluid is emptied from the bag through said tube passing into the peritoneal cavity, a portion of the connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing, and the aseptic state in the bag, which has become empty, is maintained;

after a prescribed dwell time in this state, a portion of the connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by said heated wafer and the cut surfaces are fused to each other to realize aseptic splicing, and after the used peritoneal dialyzing fluid is removed to the bag via said tube passing into the peritoneal cavity, a portion of the connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing.

### Detailed explanation of the invention

[0001]

#### Technical field of the invention

This invention pertains to a type of bag for use in continuous ambulatory peritoneal dialysis (CAPD) as a method for cleaning the blood of patients with renal failure.

[0002]

#### Prior art

CAPD is a method for cleaning blood. In this method, a peritoneal dialyzing fluid, usually in the amount of 1.5-2 L, contained in a bag is injected through a peritoneal tube spliced to an exchange tube passing into the peritoneal cavity. The peritoneal dialyzing fluid is left there for 4-8 h. During this dwell time, based on the principles of difference in osmotic pressure and diffusion, the waste and water in the blood migrate into the peritoneal dialyzing fluid so that the blood is cleaned. At present, when CAPD is performed, after injection of the peritoneal dialyzing fluid, the empty bag of peritoneal dialyzing fluid is removed; the tip of the exchange tube is sealed by threading or fitting a closing member; in the next round of exchange of the dialyzing fluid, a system having a new bag of peritoneal dialyzing fluid and an empty bag for the used fluid is employed.

[0003]

However, in the aforementioned system, an empty bag for the used fluid has to be prepared. Also, as the final number of bags that have to be disposed of is increased, the amount of the supply material and the amount of waste to be disposed are increased. This is undesirable. It has been suggested to use the first bag that contained the peritoneal dialyzing fluid as the bag to accommodate the used fluid. However, it is believed that as the interior of the bag is contaminated with bacteria, peritonitis may be caused by bacterial infection. In another proposed scheme, a small amount of sodium hypochlorite is placed in the first bag that contained the peritoneal dialyzing fluid so that it can later be used to accommodate the used fluid. However, the effectiveness in preventing peritonitis is still insufficient.

[0004]

#### Problems to be solved by the invention

The purpose of this invention is to solve the aforementioned problems of the conventional methods by providing a type of bag for peritoneal dialysis characterized by the fact that it can prevent peritonitis caused by contamination of the interior of the bag by bacteria and infection by bacteria during exchange, and it allows use of the first bag that contained the

peritoneal dialyzing fluid as the bag to accommodate the used fluid, thereby reducing the amount of waste.

[0005]

Means to solve the problems

In order to solve the aforementioned problems, this invention has the following features.

(1) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube; for this bag, the connecting tube and another tube are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through said another tube into the peritoneal cavity, the connecting tube and said another tube are separated aseptically, the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, the connecting tube and said another tube are aseptically spliced, and, after the used peritoneal dialyzing fluid is removed from the peritoneal cavity to the bag via said another tube, the connecting tube and said another tube are separated aseptically.

[0006]

(2) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube for connection to a tube passing into the peritoneal cavity; for this bag, the connecting tube and said tube passing into the peritoneal cavity are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through said tube passing into the peritoneal cavity into the peritoneal cavity, the connecting tube and said tube passing into the peritoneal cavity are separated aseptically, the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, the connecting tube and said tube passing into the peritoneal cavity are aseptically spliced, and, after the used peritoneal dialyzing fluid is removed from the peritoneal cavity to the bag via said tube passing into the peritoneal cavity, the connecting tube and said tube passing into the peritoneal cavity are separated aseptically.

[0007]

(3) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid, and it has a connecting tube; for this bag, a portion of said connecting tube and a portion of another tube are melted and cut by a heated wafer, and the cut surfaces are fused to each other to realize aseptic splicing; after the peritoneal dialyzing fluid is emptied from the bag through said another tube into the peritoneal cavity, a portion of the connecting tube and a portion of said another tube are melted and cut by said heated wafer, and

the cut surfaces are respectively fused and closed for sealing; the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, a portion of the connecting tube and a portion of said another tube are melted and cut by said heated wafer and the cut surfaces are fused to each other to realize aseptic splicing; and, after the used peritoneal dialyzing fluid is removed from the peritoneal cavity to the bag via said another tube, a portion of the connecting tube and a portion of said another tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing.

[0008]

(4) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid, and it has a tube passing into the peritoneal cavity; for this bag, a portion of said connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by a heated wafer, and the cut surfaces are fused to each other to realize aseptic splicing; after the peritoneal dialyzing fluid is emptied from the bag through said tube passing into the peritoneal cavity, a portion of the connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing; the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, a portion of the connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by said heated wafer and the cut surfaces are fused to each other to realize aseptic splicing, and after the used peritoneal dialyzing fluid is removed from the peritoneal cavity to the bag via said tube passing into the peritoneal cavity, a portion of the connecting tube and a portion of said tube passing into the peritoneal cavity are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing.

[0009]

(5) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube for connection to an exchange tube; for this bag, the connecting tube and said exchange tube are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through said exchange tube into the peritoneal cavity, the connecting tube and said exchange tube are separated aseptically, the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, the connecting tube and said exchange tube are aseptically spliced, and, after the used peritoneal dialyzing fluid is removed

from the peritoneal cavity to the bag via said exchange tube, the connecting tube and said exchange tube are separated aseptically.

[0010]

(6) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid and has a connecting tube spliced to a peritoneal tube passing into the peritoneal cavity; for this bag, the connecting tube and said exchange tube are spliced aseptically; after the peritoneal dialyzing fluid is emptied from the bag through said exchange tube into the peritoneal cavity, the connecting tube and said exchange tube are separated aseptically, the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, the connecting tube and said exchange tube are aseptically spliced, and after the used peritoneal dialyzing fluid is removed from the peritoneal cavity to the bag via said exchange tube, the connecting tube and said exchange tube are separated aseptically.

[0011]

In the invention described in said (5) and (6), the connecting tube and exchange tube are aseptically spliced, and after the used peritoneal dialyzing fluid (discharged fluid) is removed from the peritoneal cavity to the bag via the exchange tube, the connecting tube and the exchange tube are aseptically separated. In this case, the aseptic splicing and separation may be carried out using the joint that allows aseptic splicing and separation disclosed in Japanese Kokai Utility Model No. Hei 5[1993]-13454, etc.

[0012]

(7) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid, and it has a connecting tube for connecting to an exchange tube; for this bag, a portion of said connecting tube and a portion of the exchange tube are melted and cut by a heated wafer, and the cut surfaces are fused to each other to realize aseptic splicing; after the peritoneal dialyzing fluid is emptied from the bag through said exchange tube into the peritoneal cavity, a portion of the connecting tube and a portion of said exchange tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing; the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, a portion of the connecting tube and a portion of said exchange tube are melted and cut by said heated wafer and the cut surfaces are fused to each other to realize aseptic splicing; and, after the used peritoneal dialyzing fluid is removed from the peritoneal cavity to the bag via said

exchange tube, a portion of the connecting tube and a portion of said exchange tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing.

[0013]

(8) This invention provides a type of bag characterized by the following facts: the bag accommodates peritoneal dialyzing fluid, and it has a connecting tube for connecting to an exchange tube spliced to a peritoneal tube passing into the peritoneal cavity; for this bag, a portion of said connecting tube and a portion of the exchange tube are melted and cut by a heated wafer, and the cut surfaces are fused to each other to realize aseptic splicing; after the peritoneal dialyzing fluid is emptied from the bag through said exchange tube into the peritoneal cavity, a portion of the connecting tube and a portion of said exchange tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing; the aseptic state in the bag, which has become empty, is maintained, and the peritoneal dialyzing fluid is kept in the peritoneal cavity; after a prescribed dwell time, a portion of the connecting tube and a portion of said exchange tube are melted and cut by said heated wafer and the cut surfaces are fused to each other to realize aseptic splicing; and, after the used peritoneal dialyzing fluid (discharged fluid) is removed from the peritoneal cavity to the bag via said exchange tube, a portion of the connecting tube and a portion of said exchange tube are melted and cut by said heated wafer, and the cut surfaces are respectively fused and closed for sealing.

[0014]

For the bag of the invention described in said (7) and (8), a portion of the connecting tube and a portion of the exchange tube are melted and cut by the heated wafer, and the cut surfaces are fused to each other to achieve aseptic splicing; after the used peritoneal dialyzing fluid (discharged fluid) is removed from the peritoneal cavity to the bag via the exchange tube, a portion of the connecting tube and a portion of an exchange tube are melted and cut by the heated wafer, and the cut surfaces are respectively fused and closed for sealing.

[0015]

For the bag for peritoneal dialysis of this invention, in continuous ambulatory peritoneal dialysis (CAPD), aseptic splicing is performed for a connecting tube to an exchange tube that is spliced to the peritoneal tube passing into the peritoneal cavity, without invasion of bacteria from outside into the fluid channel, by means of an aseptic splicing device that melts and cuts the connecting tube [and the exchange tube] with a heated wafer, and fuses the cut surfaces to each other to realize aseptic splicing. After the peritoneal dialyzing fluid has accumulated in the peritoneal cavity, said aseptic splicing device is used, and the tips of the connecting tube of the



empty bag and the exchange tube are cut aseptically in a closed state without invasion of bacteria from the outside; the interior of the empty bag is kept aseptic; after a prescribed dwell time, the peritoneal dialyzing fluid is discharged. In this case, the connecting tube of the empty bag and the exchange tube are aseptically spliced by means of the aseptic splicing device, and the empty bag is reused as the bag for storing the used fluid.

[0016]

#### Embodiment of the invention

In the following, this invention will be explained with reference to figures. Figures 1-3 are schematic diagrams illustrating an embodiment of this invention. Figure 1 is a diagram illustrating the condition of bag (1) of this invention before use. Bag (1) is composed of bag body (11) and connecting tube (12) connected to the bag body. In bag body (11), peritoneal dialyzing fluid (14) is accommodated. Peritoneal tube (3) is inserted into the peritoneal cavity of abdomen (4) of the patient. Exchange tube (2) is connected aseptically through connecting member (6) to peritoneal tube (3). Also, clamp (5) is set on exchange tube (2) such that no leakage occurs when the peritoneal dialyzing fluid is injected into the peritoneal cavity. Tip (13) of connecting tube (12) and tip (21) of exchange tube (2) are sealed by thermally fusing the inner surfaces of the tubes.

[0017]

In this embodiment, there is no limit at all on the type of clamp (5), and any conventional CAPD, fluid transfusion, or blood transfusion type may be used. There is no special limitation on the type of connecting member (6). Any type for use in conventional CAPD may be used, as long as the shortened exchange tube operation can be replaced after several rounds of CAPD.

[0018]

Then, as shown in Figure 2, tip (13) of connecting tube (12) and tip (21) of exchange tube (2) are melted and cut by a heated wafer. Then, as shown in Figure 3, the cut surfaces are fused and are spliced aseptically. After splicing connecting tube (12) and exchange tube (2), clamp (5) is opened, and, when bag (1) is hung, peritoneal dialyzing fluid (14) in bag body (11) is injected through connecting tube (12), exchange tube (2), and peritoneal tube (3) into the peritoneal cavity. Also, when the tubes are melted and cut/spliced, it is preferred that an aseptic splicing device having a heated wafer inside it be used, such as a TSCD (registered trademark) SC-101 (manufactured by Terumo K.K.), etc.

[0019]

After injection of the peritoneal dialyzing fluid into the peritoneal cavity, clamp (5) is closed, and, as shown in Figure 4, the spliced connecting tube (12) and exchange tube (2) are melted and cut by the heated wafer. At the same time, the cut surfaces are thermally fused, and bag (1) is separated from exchange tube (2), while the interior of bag (1), the interior of exchange tube (2), the interior of peritoneal tube (3), and the interior of the peritoneal cavity are kept in the aseptic state.

[0020]

After the peritoneal dialyzing fluid has been kept in the peritoneal cavity for 4-8 h, the operation is performed in the same way as the initial operation, except that bag (1) is empty in this case. Tip (13) of connecting tube (12) and tip (21) of exchange tube (2) are melted and cut by the heated wafer, and, as shown in Figure 5, the cut surfaces are fused to effect aseptic splicing. Then, with clamp (5) open, used peritoneal dialyzing fluid (discharged fluid) (15) is discharged from the peritoneal cavity and is removed to bag (1). At this time, as the interior of bag (1) is kept in the aseptic state, it is possible to prevent peritonitis caused by bacterial contamination of bag (1) during the fluid exhaustion operation and bacterial infection in the exchange operation.

[0021]

Then, connecting tube (12) and exchange tube (2) are melted and cut by the heated wafer, and, at the same time, the cut surfaces are thermally fused. Or, only connecting tube (12) has its cut surface thermally fused, and exchange tube (2) is newly spliced to connecting tube (12) of bag (1). In this way, said CAPD can be carried out repeatedly, and bag (1) containing the used fluid is disposed of.

[0022]

There is no special limitation on the type of bag body of this invention, as long as it is made of a soft plastic that has passed the plastic bag test for fluid transfusion. More specifically, the following materials may be used: polyvinyl chloride, polypropylene, polyethylene, polyester, ethylene vinyl acetate copolymer, etc. For the various tubes, the same materials as those used for the bag body may be used as long as splicing, separation, and fusion can be carried out by the aseptic splicing device.

[0023]

There is no special limitation on the type of peritoneal dialyzing fluid accommodated in the bag of this invention. The peritoneal dialyzing fluid is prepared by dissolving in water a prescribed amount of the compounds (lactic acid, etc.) used in manufacturing the transfusion fluid, their pharmacologically tolerable salts (sodium lactate, etc.), as well as electrolytes, such as sodium chloride, potassium chloride, magnesium chloride, etc., and reduced sugars, such as anhydrous glucose, anhydrous fructose, etc. More specifically, Peritoric [transliteration] (product of the Terumo Corporation) and products with the same composition may be used. Also, in order to maintain the aseptic state, it is preferred that the sample be pasteurized beforehand. When high-pressure steam sterilization is carried out, the operation is preferably carried out at 100-130°C for 1-120 min, or more preferably, at 100-126°C for 5-60 min.

[0024]

Effect of the invention

For the bag of this invention, when it is used in CAPD, there is no need to prepare a special empty bag to accommodate the discharged fluid used in CAPD. Consequently, the quantity of bags disposed of can be reduced. Also, for the bag of this invention, as splicing and separation are performed aseptically, it is possible to maintain the aseptic state both before and during use (while peritoneal dialyzing fluid is kept in the peritoneal cavity), and it is possible to prevent peritonitis.

#### Brief description of the figures

Figure 1 is a schematic diagram illustrating the state of the bag of this invention (with peritoneal dialyzing fluid contained in it) before use.

Figure 2 is a schematic diagram illustrating the state when tip (13) of connecting tube (12) of the bag of this invention (with peritoneal dialyzing fluid contained in it) and tip (21) of exchange tube (2) are cut off.

Figure 3 is a schematic diagram illustrating the state when connecting tube (12) of the bag of this invention (with peritoneal dialyzing fluid contained in it) and exchange tube (2) are spliced, and the peritoneal dialyzing fluid is emptied from the bag of this invention.

Figure 4 is a schematic diagram illustrating the state when the spliced connecting tube (12) of the bag of this invention (when empty) and exchange tube (2) are cut.

Figure 5 is a schematic diagram illustrating the state when connecting tube (12) of the bag of this invention (when empty) and exchange tube (2) are spliced again.

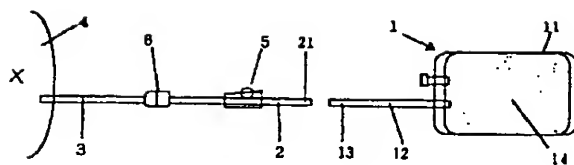


Figure 1

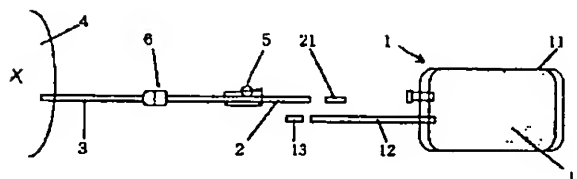


Figure 2

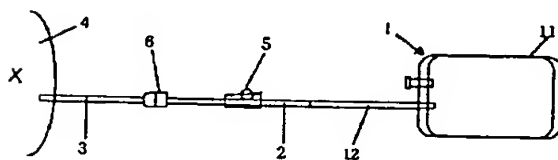


Figure 3

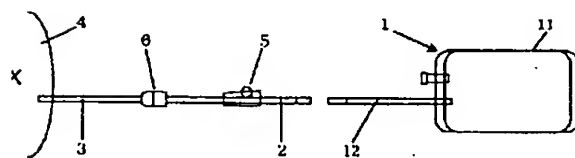


Figure 4

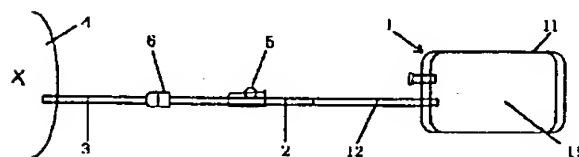


Figure 5